



ARA-US-P1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Li et al.      Group Art Unit:  
Serial No.:                      10/618,133                      Examiner:  
Filed:                              July 11, 2003  
Title:                              APPARATUS AND METHOD FOR CONTINUOUS  
   DEPYROGENATION AND PRODUCTION OF  
   STERILE WATER FOR INJECTION

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450


INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 CFR § 1.56, Applicants request that the references cited in the accompanying Form PTO/SB/08A (10-96) be considered by the examiner in the above-entitled application and made of record therein. Copies of the cited references are enclosed.

Respectfully submitted,

October 10, 2003  
Date

  
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Roberto L. Gomez

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 5

### Complete if Known

Application Number	10/618,133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	U	5,186,020		Rockefeller et al.	02/16/1993	Entire Patent
	V	5,166,123		Agui et al.	11/24/1992	Entire Patent
	w	5,104,546		Filson et al.	04/14/1992	Entire Patent
	X	5,032,265		Jha et al.	07/16/1991	Entire Patent
	Y	5,026,258		Mosley	06/25/1991	Entire Patent
	Z	5,021,391		Agui et al.	06/04/1991	Entire Patent
	AA	4,958,658		Zajac	09/25/1990	Entire Patent
	BB	4,935,150		Iida et al.	06/19/1990	Entire Patent
	CC	4,913,827		Nebel	04/03/1990	Entire Patent
	DD	4,909,942		Sato et al.	03/20/1990	Entire Patent
	EE	4,833,888		Kerner et al.	05/30/1989	Entire Patent
	FF	4,883,596		Agui et al.	11/28/1989	Entire Patent
	GG	4,858,643		Vavra et al.	08/22/1989	Entire Patent
	HH	4,810,388		Trasen	03/07/1989	Entire Patent
	II	4,772,390		Kawai et al.	09/20/1988	Entire Patent
	JJ	4,759,909		Joslyn	07/26/1988	Entire Patent
	KK	4,752,389		Burrows	06/21/1988	Entire Patent
	LL	4,673,733		Chandra et al.	06/16/1987	Entire Patent
	MM	4,648,978		Makinen et al.	03/10/1987	Entire Patent
	NN	4,610,790		Reti et al.	09/09/1986	Entire Patent

### FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

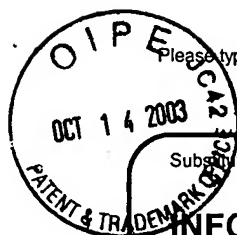
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 5

Complete if Known

Application Number	10/618133
Filing Date	07/11/2003
First Named Inventor	Lixiong Li
Group Art Unit	
Examiner Name	
Attorney Docket Number	ARA-US-P1

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		Number	Kind Code <sup>2</sup> (if known)			
	OO	4,548,716		Boeve	10/22/1985	Entire Patent
	PP	4,547,289		Okano et al.	10/15/1985	Entire Patent
	QQ	4,495,067		Klein et al.	01/22/1985	Entire Patent
	RR	4,381,239		Chibata et al.	04/26/1983	Entire Patent
	SS	4,276,177		Smith	06/30/1981	Entire Patent
	TT	4,261,834		deWinter	04/14/1981	Entire Patent
	UU	4,182,354		Bergstedt	01/08/1980	Entire Patent
	VV	4,070,289		Akcasu	01/24/1978	Entire Patent
	WW	4,069,153		Gunther	01/17/1978	Entire Patent
	XX	3,870,033		Faylor et al.	03/11/1975	Entire Patent
	YY	3,860,494		Hickman	01/14/1975	Entire Patent
	ZZ	3,648,438		Arbogast	03/14/1972	Entire Patent
	AAA	3,601,378		Hurst	08/24/1971	Entire Patent
	BBB	3,068,794		Morris et al.	12/18/1962	Entire Patent
	CCC	2,362,724		Shea	11/14/1944	Entire Patent
	DDD	2001/0050215	A1	Li et al.	12/13/2001	Entire Patent
	EEE	2003/0164339	A1	Li et al.	09/04/2003	Entire Patent

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	FFF	JP	4-114661		Yasushi et al.	04/15/1992	Entire Patent	
	GGG	JP	1-203046		Jun et al.	08/15/1989	Entire Patent	
	HHH	JP	59-112888		Kazuo et al.	06/29/1984	Entire Patent	
	III	JP	57-171403		Atsushi et al.	10/22/1982	Entire Patent	
	JJJ	WO	91/04086		Huo et al.	04/04/1991	Entire Patent	

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			Filing Date	07/11/2003
			First Named Inventor	Lixiong Li
			Group Art Unit	
			Examiner Name	
Sheet 4 of 5	Attorney Docket Number	ARA-US-P1		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	KKK	W. DICKINSON BURROWS and JAMES H. NELSON, IV Fluidmakers: Preparation of Sterile Water for Injection in a Field Setting, Journal of Parenteral Science & Technology, May-June 1993, pp. 124-129, Vol. 47 No. 3	/
	LLL	ANDREW W. COLLENTRO, Pharmaceuticals - Practical Microbial Control Techniques for Pharmaceutical Water Purification Systems, Ultrapure Water, March 2002, pp. 53-60	/
	MMM	KIYOSHI TSUJI and SUSAN HARRISON, Dry-Heat Destruction of Lipopolysaccharide: Dry-Heat Destruction Kinetics, Appl. Environ. Microb., Nov. 1978, pp. 710-714, Vol. 36 No. 5	/
	NNN	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Heat Exchangers to Avoid Contamination, Inspection Technical Guide (ITG) No. 34, July 31, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg34.html (last visited March 29, 1999)	/
	OOO	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Pyrogens, Still a Danger, Inspection Technical Guide No. 32, January 12, 1979, pp. 1-3, at www.fda.gov/ora/inspect_ref/itg32.html (last visited March 29, 1999)	/
	PPP	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), Guide to Inspections of High Purity Water Systems, pp. 1-9, at www.fda.gov/ora/inspect_ref/igs/high.html (last visited March 24, 1999)	/
	QQQ	KIYOSHI TSUJI and A.R. LEWIS, Dry-Heat Destruction of Lipopolysaccharide: Mathematical Approach to Process Evaluation, Appl. Environ. Microb., Nov. 1978, pp. 715-719, Vol. 36 No. 5	/
	RRR	HANS TRAEGER, Pharmaceuticals - The Presence of Bacteria, Endotoxins, and Biofilms in Pharmaceutical Water, Ultrapure Water, March 2003, pp. 17-22	/
	SSS	ALEX KONOPKA, Pharmaceuticals - Current Issues and System Design Considerations Affecting Pharmaceutical Water Systems, Ultrapure Water, March 2002, pp. 22-30	/
	TTT	DAVID H. PAUL, Back to Basics - The Combining of Reverse Osmosis and Ion Exchange, Ultrapure Water, July/August 2002, pp. 38-40	/
	UUU	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Bacterial Endotoxins/Pyrogens, Inspection Technical Guide (ITG) No. 40, March 20, 1985, pp. 1-10, at www.fda.gov/ora/inspect_ref/itg40.html (last visited March 24, 1999)	/

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	VVV	UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA), ITG Subject: Water for Pharmaceutical Use, Inspection Technical Guide (ITG) No. 46, December 31, 1986, pp. 1-4, at <a href="http://www.fda.gov/ora/inspect_ref/itg/itg46.html">www.fda.gov/ora/inspect_ref/itg/itg46.html</a> (last visited October 9, 2003)	/
	WWW	EUROPEAN PATENT OFFICE Abstract - Pyrogen Adsorbent and Removal of Pyrogen Using the Same, JP 4-114661, April 15, 1992	/
	XXX	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Resin Carrier, JP 1-203046, August 15, 1989	/
	YYY	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen From Aqueous Solution, JP 59-112888, June 29, 1984	/
	ZZZ	EUROPEAN PATENT OFFICE Abstract - Removal of Pyrogen in Water, JP 57- 171403, October 22, 1982	/

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